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Agriculture

Food Safety
And Inspection
Service

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AUDIT REPORT FOR NICARAGUA

SEPTEMBER 18 THROUGH SEPTEMBER 22, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Nicaragua's meat inspection system from September 18 through September 22, 2000. All three establishments certified to export meat to the United States were audited. All three of these were slaughter establishments and conducting processing (boning and cutting) operations.

The last audit of the Nicaragua meat inspection system was conducted in September 1999. Three establishments were audited; two were recommended for re-review and one was acceptable.

During calendar year 2000 (up to August 31st), Nicaragua exported 14, 806, 713 pounds of fresh beef and beef products, beef edible organs, and beef processed products to the U.S. Port-of-entry (POE), rejections were 131, 105 pounds for processing defects, miscellaneous defects, contamination, pathological defects, and transportation damage and missing shipping marks.

The principal concerns with Nicaragua's meat inspection system at the time of 1999 audit were the following:

- Nicaragua's inspection personnel were not performing the required records and process verification procedures to determine the implementation, effectiveness, and maintenance of the establishment's Sanitation Standard Operating Procedure (SSOP)/ equivalent programs in Establishments 4, 5 and 8.
- The SSOP did not include walls, overhead equipment, and ceilings in the slaughter, boning room, and offal room in all establishments.
- The *Escherichia coli* (*E. coli*) test results were not being recorded using statistical process control chart.
- There was also inadequate implementation of Hazard Analysis Critical Control Point (HACCP) plan.

All above concerns and deficiencies have been addressed and corrected.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Nicaragua's national meat inspection officials to discuss oversight programs and practices, including enforcement and compliance activities. The second entailed an audit of a selection of records in the meat inspection offices of the facilities of the on-site visits. The third was conducted by on-site visits to establishments. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for

the presence of microbiological contamination with *Salmonella* and *E. coli*. Nicaragua uses government laboratories for microbiological testing.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program; and (5) enforcement controls, including the testing program for *Salmonella* species. Nicaragua's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in all three establishments audited. Details of audit findings and observations, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

Entrance Meeting

On September 18, 2000, an entrance meeting was held at the offices of the Ministerio Agropecuario y Forestal (MAF) at Nicaragua and was attended by Dr. Pedro Blandon, Chief, Meat Inspection Division, Dr. Rene Roa, Deputy Chief, Meat Inspection of MAF; Mrs. Maria Soler, Interpreter and Dr. Suresh Singh, International Audit Staff Officer of the Technical Service Center, Food Safety and Inspection Service (FSIS-USDA). Topics of discussion included the following:

1. Travel arrangements and itinerary within Nicaragua.
2. Briefing of status of recent correspondence between FSIS and MAF.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Nicaragua's inspection system in September 1999.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the supervisory inspection officials who

normally conduct the periodic reviews and audits for compliance with U.S. specifications. The FSIS auditor (hereinafter called “the auditor”) observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the establishments during on site visits. The records review focused primarily on food safety hazards and included the following:

- Internal review reports and compliance check/list.
- Compliance visits to establishments that were certified to export to the U. S.
- Training records for inspectors.
- Records such as generic labels, and animal raising claims.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials and veterinary coverage.
- Export product inspection and control including export certificates.

No concerns arose as a result of the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Nicaragua as eligible to export meat products to the United States were full-time, MAF employees, receiving no remuneration from either industry or establishment.

Establishment Audits

Three establishments were certified to export meat products to the United States at the time this audit was conducted. All three establishments were visited for on-site audits. In all establishments visited, both Nicaragua inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Intra-laboratory quality assurance procedures, including sample handling.
2. Methodology.

The Government (MAF), Nicaragua Residues Laboratory in Managua was audited on September 21, 2000. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation, print outs, minimum detection

levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable.

Nicaragua's microbiological testing for *Salmonella* and *E. coli* was being performed in government laboratories and the procedures and methodology were acceptable.

Establishment Operations by Establishment Number

The following operations were being conducted in the three establishments:

Beef slaughter, cutting, and boning - two establishments (0004 and 0005)

Beef slaughter, cutting and boning (no production) – one establishment (0008) not operating at present time because of financial problem but soon to be opened.

SANITATION CONTROLS

Based on the on-site audits of establishments, Nicaragua's inspection system had controls in place for water potability, hand washing facilities, sanitizers, pest control program, temperature control, lighting, and ventilation. Basic establishment facilities, condition of facilities and equipment, product protection and handling and establishment sanitation programs were acceptable.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements.

Cross-Contamination

1. Product accumulation (Boneless beef) on the boning table was observed in Establishment 4, and plastic trays were kept on the top of the product. Veterinary officials took corrective actions by removing the trays and keeping the flow of the product by collecting the product for storage.
2. Liver and hearts were being cleaned in a tray without drain for dirty water in the edible organ room of Establishment 5. Veterinary officials and establishment officials discussed and agreed to replace the tray.
3. Peeling paint, cracked floor and rust spots were observed in the carcass cooler in Establishment 8. Veterinary officials and establishment officials discussed this issue and corrective action will be taken before establishment starts the operation.

Product Handling and Storage

No deficiency was observed in this area.

Personnel Hygiene and Practices

In all establishments, employees were observed to follow good personnel hygiene practices.

ANIMAL DISEASE CONTROLS

Nicaragua's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. This is of special interest to all those with a stake in Nicaragua's animal production industries.

RESIDUE CONTROLS

Nicaragua's National Residue Testing Plan for 2000 was being followed and was on schedule. The Nicaragua inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the Nicaragua's inspection system had controls in place to ensure adequate product protection and processed product controls.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program and met FSIS requirements. The data collection instrument used accompanies this report (Attachment B).

Testing for Generic *E. coli*

Nicaragua has adopted the FSIS regulatory requirements for generic *E. coli* testing. All of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements for generic *E. coli* testing with the exception of the following equivalent measures:

1. **SAMPLE COLLECTOR:** Government takes samples.
 - There is a clearly written sampling plan with instruction for sample collection and processing that is being followed.
 - The government has a means of ensuring that sample collection activities are appropriate.
 - The government uses the test results to verify establishment slaughter, processing and dressing controls for fecal contamination.
2. **LABORATORIES:** Government Laboratories.

- The method is a quantitative method of analysis.
- The method is approved by the AOAC International .

ENFORCEMENT CONTROLS

Inspection System Controls

The Nicaragua inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat re-inspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled.

Adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

All of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program and criteria used in the equivalency determination. The data collection instrument used accompanies this report (Attachment D).

Nicaragua has adopted the FSIS regulatory requirements for *Salmonella* testing.

Species Verification Testing

At the time of this audit, Nicaragua was not exempt from the species verification testing requirements. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

The National Meat Inspection Officials were performing the in-depth reviews and audits.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, the Chief Meat Inspection Officer is empowered to conduct an in-depth review, he formulates a plan for corrective actions and preventive measures.

Enforcement Activities

Meat Inspection officials carry out enforcement activities. The Chief Meat Inspection Officer has the sole power to initiate all enforcement actions.

Exit Meeting

An exit meeting was conducted in Managua on September 21, 2000. The Nicaraguan participants were Dr. Antinio Epinosa, Director, Animal Health; Dr. Pedro Blandon, Chief of Meat Inspection; Dr. Rene Roa, Deputy Chief, Meat Inspection; Mrs. Maria K Soler, translator and Dr. Suresh Singh, International Audit Staff Officer of FSIS.

The following topics were discussed:

1. Audit findings and observations of the auditor as reported in the cross contamination section of this report.
2. Enforcement reports of USDA and requested the same type of enforcement report from Nicaraguan authorities.

Additionally, Mrs. Isabella Detwiller, Economic Officer, American Embassy in Managua was briefed regarding Nicaragua's meat inspection audit findings.

CONCLUSION

The inspection system of Nicaragua was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Three establishments were audited and all were acceptable. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. Suresh P. Singh
International Audit Staff Officer

(signed) Dr. Suresh P. Singh

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing.
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory audit form
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. Identified	7. Documentation done daily	8. Dated and signed
04	√	√	√	√	√	√	√	√
05	√	√	√	√	√	√	√	√
08	√	√	√	√	√	√	√	√

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
2. The plan describes corrective actions taken when a critical limit is exceeded.
3. The HACCP plan was validated using multiple monitoring results.
4. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. actions are described	9. Plan validated	10. Adequate verific. Procedures	11. Adequate documentation	12. Dated and signed
04	√	√	√	√	√	√	√	√	√	√	√	√
05	√	√	√	√	√	√	√	√	√	√	√	√
08	√	√	√	√	√	√	√	√	√	√	√	√

Data Collection Instrument for Generic *E. coli* Testing

Each establishment ~~was~~ evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The equivalent carcass site and collection methodology (Swab) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method .
9. The results of the tests are being recorded on a process control chart but on a table form showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
04	√	√	√	√	no	√	√	√	√	√
05	√	√	√	√	√	√	√	√	√	√

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The equivalent carcass site and method is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
04	√	√	N/A	√	√	√
05	√	√	√	√	√	√